

R090106

MAR 31 2009

510(k) Summary of Safety and Effectiveness

(As Required by 21 C.F.R. §807.92)

Applicant: Danville Materials, Inc.
2021 Omega Dr.
San Ramon, CA 9458

Contact Person: Criag R. Bruns
Phone 925 838-7940
Fax 925 838-0944
e-mail: cbruns@daneng.com

Date of Summary:

Device Name: Prelude One

Common Name: Agent, Tooth Bonding, Resin

Classification Names:	<u>Regulation Number</u>	<u>Product code</u>
	21 CFR 872.3200	KLE

Device Description: Prelude One is a dental bonding agent used to restore all classes of cavities.

Predicate Device: The device is substantially equivalent to other legally marketed devices in the United States including Clearfil S³ and Xeno IV.

Intended Use: Prelude One is a light cured adhesive designed for direct restorations, i.e. composites and compomers to enamel and/or dentin, composite repairs, porcelain repairs and post and core build-up materials, and indirect restorations such as veneers, onlays, inlays, crowns and bridges.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 2009

Ms. Lindsay Tilton
Document Control/Marketing Associate
Danville Materials, Incorporated
3420 Fostoria Way, Suite A-200
San Ramon, California 94583

Re: K090106
Trade/Device Name: Prelude One
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: November 12, 2008
Received: January 1, 2009

Dear Ms. Tilton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Ginette Y. Michaud, M.D.

Acting Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number: ~~Pending~~ K090106

Device Name: Prelude

Indications For Use:

Prelude One is a light cured adhesive designed for direct restorations, i.e. composites and compomers to enamel and/or dentin, composite repairs, porcelain repairs and post and core build-up materials, and indirect restorations such as veneers, onlays, inlays, crowns and bridges.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Rayson

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090106